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THE PROCTER & GAMBLE COMPANY
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EXAMINER

SCHLENTZ, NATHAN W

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1616

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Status of Claims

Claims 1, 15, 17, 20, 34 and 38 have been amended in an amendment filed 07 July 2008. Claims 8-14, 27-33 and 39 are withdrawn as being drawn to a non-elected invention. As a result, claims 1-7, 15-26 and 34-38 are examined herein on the merits for patentability. No claim is allowed at this time.

Withdrawn Rejections

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Objections

1. Claim 35 is objected to because of the following informalities: the claim does not end with a period. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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1. Claims 20-26 and 34-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by “essentially free of tomato flavor”. The term “essentially free of” is a term of degree that is not defined in the specification. One skilled in the art would be unable to determine what range of tomato flavor would be within the scope of the instant claims. Therefore, the scope of the instant claims is not clear. For the purposes of search and examination, the examiner is construing the claims in the absence of the limitation “essentially free of tomato flavor”.

Response to Arguments

Applicants argue on page 8 of their Remarks filed 07 July 2008 that page 5, lines 23-26 and page 6, lines 1-9 of the specification discussed the phrase “essentially free of” with respect to sugars, and one of ordinary skill in the art would be able to understand what is meant by the phrase “essentially free of tomato flavor”.

The examiner respectfully disagrees. The specification discusses on page 5, line 23 to page 6, line 9 that sugar can be deleterious to the health of a variety of companion animals, such as overweight or senior animals, or those prone to pre-diabetic or diabetic conditions. Therefore, the composition is essentially free of sugars (i.e., less than about 10%, less than about 5%, less than about 2%, less than about 1%, and less than about 0.5%). However, the instant specification does not define a relationship between sugars and tomato flavor by which one skilled in the art would understand that “essentially free of tomato flavor” has the same physical limitations on the amount

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present as “essentially free of sugars”. By tomato flavors the instant specification includes fresh tomato, chopped tomato, pureed tomato, tomato paste, and other natural and artificial tomato flavors. It is not clear from the instant specification that by stating that the composition has less than about 10% sugars, it is also intended that the composition has less than about 10% fresh tomato, chopped tomato, pureed tomato, tomato paste, and other natural and artificial tomato flavors. Therefore, the instant claims are not clearly defined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tinembart et al. (US 2002/0058683) in view of Chu et al. (US 2002/0025325).

Applicant claims:

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Applicants claim a kit comprising a compartmentalized container, a 1st composition comprising a medicament housed in a 1st compartment, and one or more compositions housed in a compartment other than said 1st compartment comprising a flavorant and water, wherein the composition is essentially free of tomato flavor. It is noted that claim 38 does not claim the presence of beet pulp within the 1st composition or the other composition(s).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Tinembart et al. teach a veterinary preparation for fleas comprising lufenuron and nitenpyram, wherein oral administration of a liquid composition comprising lufenuron and nitenpyram effectively controlled flea infestation ([0057]-[0058]). Tinembart et al. also teach that because of its simple practicability, oral usage is one of the preferred subjects of the invention, especially the administration of tablets or suspensions, wherein additives are used to encourage willing consumption by the host animal, such as suitable odorous substances, flavorings and/or taste substances ([0061]-[0063]). Tinembart et al. teach that the lufenuron and nitenpyram are present from 0.1-95 wt.% and a liquid, physiologically acceptable carrier is present from 99.9-5 wt.% ([0078]). Tinembart et al. teach that the dosages may be carried in specially designed packs for administration by the veterinarian or keeper ([0075] and [0087]).

Furthermore, Tinembart et al. teach an emulsifier concentrate example comprising 20 wt.% active substances (i.e. lufenuron and nitenpyram), 20 wt.% emulsifier, and 60 wt.% solvent, and the composition is diluted with water to the desired

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concentration (Example 6). Also, Tinembart et al. teach drink additive examples comprising 15 wt.% of active ingredient, 10 wt.% of the active ingredient in diethylene glycol monoethylether, 10 wt.% in polyethylene glycol 300, and 5 wt.% in glycerol (Example 7).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Tinembart et al. do not explicitly teach the liquid preparation comprising lufenuron and nitenpyram wherein the composition is essentially free of tomato flavor. However, Chu et al. teach that flavorants for use in the oral vaccine formulations to be administered to animals through drinking water include fruit flavors preferred for horses, cats and dogs, meat flavors preferred for dogs and cats, and fish flavors preferred for cats ([0029]).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to prepare liquid formulations for oral administration of lufenuron and nitenpyram comprising flavorings and water, as taught by Tinembart et al., wherein the flavorings comprise fruit flavors preferred for horses, cats and dogs, meat flavors preferred for dogs and cats, and fish flavors preferred for cats, as reasonably taught by Chu et al. Also, one of ordinary skill in the art would have been motivated to package the compositions in specially designed packs, or kits, for the veterinarian or keeper to administer the predetermined dosage at predetermined intervals, as reasonably taught

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by Tinembart et al. With regard to the instantly claimed kits comprising a plurality of compartments, it would have been *prima facie* obvious for one of ordinary skill in the art to provide a kit comprising multiple compartments in order to have several dosages within one pack or kit, which need to be administered according to a dosage scheme, as taught by Tinembart et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on pages 9-11 that Tinembart and Chu, either alone or in combination, fail to teach kits comprising compartmentalized containers wherein a composition comprising a medicament is housed in a compartment that is separate from a compartment housing a composition comprising a flavorant, water, and is essentially free of sugars or tomato flavors. However, the examiner respectfully argues that, as instantly claimed, the 1st composition *comprising* a medicament within said 1st compartment, and the one or more compositions *comprise* of a flavorant and water within said compartment other than the 1st compartment, can be the same composition in two or more compartments. The 1st composition *comprising* a medicament can also contain other ingredients, such as flavorants and water; and the one or more compositions *comprise* of a flavorant and water can also contain other ingredients, such

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as a medicament. Therefore, a composition comprising a medicament, flavorant, and water within two or more compartments within a kit would read on said claim.

The transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) (“like the term ‘comprising,’ the terms ‘containing’ and ‘mixture’ are open-ended.”).[<] *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) (“The transition ‘comprising’ in a method claim indicates that the claim is open-ended and allows for additional steps.”); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“comprising” leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”).

New Grounds of Rejections

1. Claims 1-5 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. (US 2002/0025325) in view of Burkhalter et al. (The Journal of Nutrition,

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2001), Sunvold et al. (Journal of Animal Science, 1995), Fahey et al. (Journal of Animal Science, 1990), Sunvold '258 (US 5,932,258), Jezek et al. (Chemical and Biochemical Engineering Quarterly, 1996), and Desforges et al. (US 5,252,136).

Applicant's claims

Applicants claim a liquid composition comprising lufenuron, a flavorant and water, wherein the composition is essentially free of sugars or tomato flavor.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Chu et al. teach compositions for oral vaccination of healthy animals through drinking water or syrups comprising admixing a palatable flavorant with a vaccine formulation in order to promote self-administration of the vaccine formulation and/or to prevent rejection of the formulation when administered by an animal handler (Abstract). Chu et al. teach an example wherein the lyophilized vaccine is re-suspended in a flavored diluent, mixed with 5 liters milk solution containing non-fat dry milk, and then further diluted with 7 liters of water ([0102]). Also, Chu et al. teach that flavorants for use in the vaccine formulations include fruit flavors preferred for horses, cats and dogs, meat flavors preferred for dogs and cats, and fish flavors preferred for cats ([0029]).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Chu et al. do not teach the addition of beet pulp to their composition, as instantly claimed. However, Burkhalter et al. teach that beet pulp is the most common source of fiber added to commercial dog diets (page. 1979, left column, lines 8-10 after the table

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description). Sunvold et al. teach that diets containing moderately fermentable fiber provide fermentation end products that may be important in maintaining the health of the gastrointestinal tract of the cat, and beet pulp represents a moderately fermentable fiber source (Abstract; pg. 2335, left column, last sentence; pg. 2338, left column, lines 40-55 without counting spaces). Fahey et al. teach beet pulp levels up to 7.5% of diet DM appear acceptable as a dietary fiber source in a meat-based canine diet (Abstract). Sunvold '258 teach beet pulp is a fermentable fiber which intestinal bacteria present in the animal can ferment to produce significant quantities of short-chain fatty acids (col. 3, ll. 48-54). Jezek et al. teach the production of soluble dietary fibers from sugar beet pulp (Title and Abstract). Desforges et al. teach water-soluble fiber obtainable by treating sugar beet with water free from chemical reagents at ambient temperature and at an elevated temperature (Abstract). Desforges et al. further teach that commercial sources of dietary fiber from sugar beet pulp are known, wherein araban is one example of a fraction of the soluble fiber from sugar beet, and water-soluble beet fiber is also found in beet molasses (col. 1, l. 55 to col. 2, l. 5). Desforges et al. also teach that soluble sugar beet fiber has cholesterol lowering properties (i.e., hypocholestromic effect), and a beneficial effect on blood glucose and mineral availability (col. 2, ll. 13-17).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to add beet pulp fiber to the composition of Chu et al.

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because beet pulp fiber is well-known as a commercial source of dietary fiber for use in pet foods, and soluble beet fiber has cholesterol lowering properties (i.e., hypocholestromaemic effect), and a beneficial effect on blood glucose and mineral availability, as reasonably taught by Desforpes et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claims 1-7, 15-26 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tinembart et al. (US 2002/0058683) in view of Chu et al. (US 2002/0025325) and Burkhalter et al. (The Journal of Nutrition, 2001), Sunvold et al. (Journal of Animal Science, 1995), Fahey et al. (Journal of Animal Science, 1990), Sunvold '258 (US 5,932,258), Jezek et al. (Chemical and Biochemical Engineering Quarterly, 1996), and Desforpes et al. (US 5,252,136).

Applicant's claims

Applicants claim a liquid composition comprising lufenuron, a flavorant and water, wherein the composition is essentially free of sugars or tomato flavor.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The teachings of Tinembart et al. and Chu et al. are discussed above and incorporated herein by reference.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Tinembart et al. do not teach adding beet pulp to their compositions, as instantly claimed. However, Burkhalter et al. teach that beet pulp is the most common source of fiber added to commercial dog diets (page. 1979, left column, lines 8-10 after the table description). Sunvold et al. teach that diets containing moderately fermentable fiber provide fermentation end products that may be important in maintaining the health of the gastrointestinal tract of the cat, and beet pulp represents a moderately fermentable fiber source (Abstract; pg. 2335, left column, last sentence; pg. 2338, left column, lines 40-55 without counting spaces). Fahey et al. teach beet pulp levels up to 7.5% of diet DM appear acceptable as a dietary fiber source in a meat-based canine diet (Abstract). Sunvold '258 teach beet pulp is a fermentable fiber which intestinal bacteria present in the animal can ferment to produce significant quantities of short-chain fatty acids (col. 3, ll. 48-54). Jezek et al. teach the production of soluble dietary fibers from sugar beet pulp (Title and Abstract). Desforges et al. teach water-soluble fiber obtainable by treating sugar beet with water free from chemical reagents at ambient temperature and at an elevated temperature (Abstract). Desforges et al. further teach that commercial sources of dietary fiber from sugar beet pulp are known, wherein araban is one example of a fraction of the soluble fiber from sugar beet, and water-soluble beet fiber is also found in beet molasses (col. 1, l. 55 to col. 2, l. 5). Desforges et al. also teach that

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soluble sugar beet fiber has cholesterol lowering properties (i.e., hypocholestromaemic effect), and a beneficial effect on blood glucose and mineral availability (col. 2, ll. 13-17).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to add beet pulp fiber to the composition of Tinembart et al. because beet pulp fiber is well-known as a commercial source of dietary fiber for use in pet foods, and soluble beet fiber has cholesterol lowering properties (i.e., hypocholestromaemic effect), and a beneficial effect on blood glucose and mineral availability, as reasonably taught by Desforbes et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new grounds of rejections presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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NWS

/John Pak/
Primary Examiner, Art Unit 1616